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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hanan Keren

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,483	Applicant(s) KEREN ET AL.	
	Examiner PATRICIA C. MALLARI	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75,77-105,107-117 and 119-145 is/are pending in the application.
- 4a) Of the above claim(s) 78,85-87,108,117 and 119-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75,77,79-84,88-105,107 and 109-116 is/are rejected.
- 7) ☒ Claim(s) 111-114 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/8/09,1/19/10,5/12/10,6/14/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims.

Election/Restrictions

This application contains claims 117 and 119-145, drawn to an invention nonelected with traverse in the reply filed on 6/16/09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

The information disclosure statements filed 11/8/09, 1/19/10, 5/12/10, and 6/14/10 have been considered.

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75, 77-84, 88-104, 115, and 116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 75 recites, "a mixed radiofrequency signal radiofrequency sum and a radiofrequency difference". It is unclear what is meant by this limitation. Based on the amendments made in the other independent claims of the application, it appears that the applicants may have meant to recite "a mixed radiofrequency signal having a radiofrequency sum and a radiofrequency difference". The claim is being interpreted as such for the purpose of this examination only. The applicants should clarify in any case.

Claim 79 recites, "said remaining portion". Neither claim 79 nor claim 75, upon which claim 79 depends, has sufficient antecedent basis for the limitation. Claim 75 does recites "a portion of said mixed radiofrequency signal" on the last two lines of the claim. However, it is unclear whether "said remaining portion" recited in claim 79 might refer to the portion recited on the last two lines of claim 75, the portion of the signal left over after the portion is filtered out, or neither. Applicants should clarify. Claims 82, 103 and 104 contain similar language and, therefore, suffer from the same problem. Claims 115 and 116 contain similar language (although they depend from claim 105 rather than claim 75) and, therefore, suffer from the same problem.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 75, 77, 79, 80, 88-96, 101, 102, 105, 107, 109, and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,642,734 to Ruben et al. Regarding claims 75 and 105, Ruben teaches a system comprising a radiofrequency generator 34 for generating output radiofrequency signals (col. 5, lines 20-30 of Ruben). A plurality of electrodes 48A, B 50A, B are designed to be connectable to the skin of the subject and transmit output radiofrequency signals to the organ and sense input radiofrequency signals of the organ (figs. 5A & B, 6; col. 5, lines 47-53 of Ruben). A mixer electrically communicates with the generator and some of the electrodes and mixes the output signals and input signals to provide a mixed radiofrequency signal indicative of the blood flow (see entire document, especially figs. 6, 12; col. 6, lines 11-34; col. 8, line 12-col. 9, line 52 of Ruben). The radiofrequency signal has a radiofrequency sum and a radiofrequency difference (see entire document, especially figs. 6, 8; col. 7, lines 51-col. 8, line 52; col. 9, lines 1-41 of Ruben). Electronic circuitry filters out a portion of the mixed signal (col. 7, lines 3-17; col. 7, line 51-col. 8, line 37 of Ruben).

Regarding claims 77 and 107, the electronic circuitry comprises a low pass filter for filtering out the radiofrequency sum (see entire document, especially fig. 8; col. 7, line 51-col. 8, line 51 of Ruben).

Regarding claims 79 and 109, the circuitry comprises a digitizer 120, wherein the digitizer is capable of digitizing any radiofrequency signal (col. 7, lines 22-23 of Ruben). Applicants should note that “for digitizing . . .” is merely “intended use” language.

Regarding claims 80 and 110, the electronic circuitry is designed and constructed so as to minimize sensitivity of the input radiofrequency signals to impedance differences between the plurality of electrodes and the organ of the subject (see entire document, especially figs. 5A, 5B, and 11 of Ruben), wherein applicants disclose the use of two input leads as opposed to one as minimizing effects of impedance differences between the electrodes and the body (see instant disclosure, especially p. 26, lines 23-26).

Regarding claim 88, the language in this claim appears to merely describe a method step describing a step of selecting the number of electrodes, wherein such a method limitation fails to further limit the apparatus of claim 11. At best, the language may be considered “product by process” language wherein the claim is evaluated based on the result of such a step rather than the accomplishment of the step itself. In such a case, the end result of such a step and the invention of Ruben are the same.

Regarding claims 89-91, the plurality of electrodes comprises two, three, or four electrodes (figs. 5A, B of Ruben).

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Regarding claims 92 and 93, at least a portion of the electrodes comprises at least one elongated conducting material constructed and designed to wind at least a portion of an external organ of the subject (see entire document, especially figs. 5A, 5B, 11 of Ruben). As to the language "so as to have a constant sensitivity to electrical signals transmitted through said electrodes, irrespective of an orientation of said electrodes on said external organ", the applicants should note that this is merely "intended use" and/or "results" language, which cannot be relied upon to define over the prior art of record, since Ruben, teaches the claimed structural features and their recited relationships. It is submitted that since Ruben teaches electrodes constructed and designed as claimed to wind at least a portion of the organ, then the electrodes must have a constant sensitivity as claimed.

Regarding claim 94, at least a portion of the plurality of electrodes comprises an attaching material (see entire document, especially col. 5, lines 57-64 of Ruben).

Regarding claim 95, said external organ is a leg or an arm (see entire document, especially col. 5, lines 47-59 of Ruben).

Regarding claim 96, a bioimpedance detector electrically communicates with at least a portion of the electrodes for detecting a voltage between a first and second location of the subject and for generating the input signals in response to the voltage, wherein the input signals are indicative of impedance (col. 5, line 45-col. 6, line 47 of Ruben).

Regarding claims 101 and 102, the system comprises a display device, wherein a personal computer generally refers to the system built around a microprocessor for

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personal use, including the input/output devices and peripherals that a general user would require, wherein such device include a display. With further regard to claim 102, a general display for a personal computer is certainly capable of displaying the blood flow as a function of time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 103, 104, 115, and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruben, as applied to claims 75, 79, 80, 88-96, 101, 102, 105, 109, and 110 above, and further in view of US 4537200 to Widrow. Ruben lacks increasing the signal-to-noise ratio by at least 10 or 20 dB. However, Widrow discloses acquiring a bioelectrical signal and filtering it so as to increase the signal-to-noise ratio by at least 20 dB, wherein such filtering is accomplished by electronic circuitry (see entire document, especially the abstract; col. 6, lines 21-34 of Widrow). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine Widrow with Ruben in order to reduce noise, thereby acquiring a more accurate signal.

Response to Arguments

Applicant's arguments filed 4/6/10 have been fully considered but they are not persuasive. The applicants argue that Ruben fails to teach mixing input and output signals to provide a mixed signal having a radiofrequency sum and a radiofrequency difference, and filtering of a portion of the mixed signal. The rejection set forth above shows that Ruben indeed teaches these features of the claimed invention.

It is further noted that the changes to claims 75 and 105 do not make the claims commensurate in scope with previous claims 76 and 106, especially in that previous claims 76 and 106, for example, required that the mixer provide a radiofrequency signal, a radiofrequency sum, and a radiofrequency difference separately and the current language of claims 75 and 105 do not.

Allowable Subject Matter

Claims 81, 82-84, 97-100 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 111-114 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

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Regarding claims 81 and 111, the primary reason for allowance is the inclusion of the differential amplifier characterized by an impedance larger than the impedance differences between the plurality of electrodes and the organ of the subject, in combination with all of the other limitations of the claims, which is not taught or fairly suggested by the prior art of record.

Regarding claims 82-84 and 112-114, the primary reason for allowance is the inclusion of the data processor calculating at least one of stroke volume, cardiac output, brain intraluminal blood flow, or artery blood flow rate using a remaining portion of the mixed radiofrequency signal, wherein the remaining portion is the portion of the signal remaining after the portion recited in claim 75 is filtered out, in combination with all of the other limitations of the claim, which is not taught or fairly suggested by the prior art of record.

Regarding claim 97, the primary reason for allowance is the inclusion of the at least one sensor for sensing voltage, said sensor being constructed and designed for generating signals having a magnitude which is a function of blood flow in, from, or to the organ, in combination with a separate bioimpedance detector for detecting a voltage between a first location and a second location and for generating input radiofrequency signals in response to said voltage, and further in combination with all of the other limitations of the claim, which is not taught or fairly suggested by the prior art of record.

Regarding claims 98-100, the primary reason for allowance is the inclusion of a differentiator for performing at least one-time differentiation to provide a respective

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derivative of the impedance between the first and second locations, in combination with all of the other limitations of the claim, which is not taught or fairly suggested by the prior art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735